IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant: Nemenov
Title: Portable Laser and Process for Producing Controlled Pain

Examiner: Johnson III, Henry M

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Information Disclosure Statement

Commissioner for Patents
PO Box 1450
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Sir:

Attached is a completed Form PTO/SB/08 (A and B) and copies of pertinent references cited thereon. A check for $180 for the fee required under Section 117(p) is attached.

A summary to the five referenced papers and a discussion of their relevance is provided below:

1. J.Mor A. Carmon. Laser emitting **radiant heat** for pain research. 1975, Pain 1 233-37

It is a first paper of describing of pain stimulator based on laser (CO2) for pain research. The parameters of irradiation 10.2 microns wavelength, pulse duration from 5 ms, beam diameter 20 mm. The authors suggested the use of CO2 laser to replace radiant heat. CO2 laser, chopper system to generate pulses, safety electronic to control chopper are described in the paper. The authors mentioned they managed to evoke sensation "from light thermal puff to a strong localized pain similar to a pinprick. Skin erythema was usually followed the stimulation.

The CO2 laser provides a general application to heat skin heating a relatively large region of skin so it cannot be used to stimulate a **"single nerve or a portion of a single nerve"** as claimed in the only outstanding independent claim. It cannot be used to distinguish pink prick pain and burning pain (i.e. A-dela and C fiber/nociceptor activation).

2. R.A. Meyer, R. E. Walker, and V. B. Mountcastle. A laser Stimulator for the study of cutaneous thermal and sensations.1976, IEEE Trans. On Biomed. Eng. 23, 54-60

A CO2 laser based stimulator with temperature control was described in the paper. The parameters of stimulation: pulse duration from 150 ms, beam diameter 7 mm. Accuracy of temperature control and stabilization are +/- 0.1 C. The authors, especially selected laser with wavelength more than 2 microns to avoid reflection from tissue. It was experimentally shown that CO2 laser induced temperature on surface could be in 10 times higher compared to 500 microns depth (area of location of nociceptors) for pulses with duration less 500 ms for water based model. The system occupied a full room.

Thefore, pain threshold power for CO2 lasers are usually higher compared to threshold power of skin lesion generation. The system described in the paper system and methods do not interfere with the claims of the diode laser based system in the present application. Like the first reference, this paper does not describe a system or method that can be used used to stimulate a **"single nerve or a portion of a single nerve"** as claimed in the only outstanding independent claim.

3. a). T.K. Bauman and M.E. Martenson. Thermosensitivity of cultured trigeminal neurons. 1994 Soc. Neoroscci. (Abstract) 20, 1379 and 3. b). T.K. Bauman, K. Vixie, and B. Adams. 1994 Biophysics Journal (Abstract) 66, 442

In this abstract briefly describes heat stimulation of trigeminal neurons with heat pulses duration 3–10 sec. The system was described in baumann et al., Biiophs. J. 66: 442, 1994 as follows: The system consisted "of a 970 nm semiconductor laser (1 W max output) and a optic fiber terminated by miniature black-body radiator (75 microns diameter). The black body was "a quartz fiber drawn to a fine ti and coated with silicon carbide and potassium silicate."

In this application diode laser irradiation was used to heat a blackened tip of fiber. The Significant laser energy does not penetrate to location of nerve cell. The heating of the nerve is a contact type of heat stimulation and laser irradiation was used to deliver energy to absorber at the end of fiber. This system and process in far different from the system describe and claimed by Applicants where nerve stimulation is provided directly by the energy of the laser beam. There is nothing in this paper to suggest the process as claimed in the outstanding claims.

4. K Jimbor, K. Noda, K. Suzuki, K. Yoda. Suppresive effects of low-power laser irradiation on bradykinin evoked action potentials in cultured murine dorsal root gandlion cells. Neuroscience Letters 240 (19998) 93-6.

As the title of this paper suggest the researchers are **suppressing** not **stimulating** the the murine dorsal root gandlion cells.Low power laser diode radiation of 830 nm, 16.2 mW was used to irradiate DRG neurons in vitro -. These parameters of irradiation do not heat and cannot activate the nerve **to produce a single mode stimulation of the nerve** as claimed by Applicants in all outstanding claims. The power of their laser was only 16.2 mW as compared to Applicants' power of in the range from tenths of watts to up to 2 to 20 watts.

Thus, there is nothing in this paper to suggest the present invention as currently claimed by Applicants.

5. N. Wittenburg and R. Baumeister. Thermal avoidance in Caenorhaditis elegants:An approach to the study of nociception. PNAS, Neurobiology (1999)96, 10477-82

Low-power diode laser***: 685 nm, 50 mW*** was coupled to a microscope. The laser beam was 30 microns. C. elegans is a nematode. The radiation was directed to different part of body and withdrawal reaction were observed. The reaction to laser radiation was compared to reaction of electronically heated tip of metal. It is unclear that pulse duration was used. Authors measured temperature induced at Agar model of tissue total ~ 33 C.

The intensity parameters of diode laser irradiation are essentially less compared to parameter of activation nerve fiber (nociceptors) in humans, rodents, and in vitro heat sensitive cell activation but was sufficient for thermal activation of small area 30 microns. A confirmation that authors had thermal activation was received by comparison of reaction to heated metal needle and application of capsaicin, chemical that is usually decrease threshold temperature of activation of some heat sensitive neuron.

The peripheral nerve system of C. elegans are primitive (Sulston, JE and White, JG (1988), "Parts list", in *The Nematode* Caenorhabditis elegans, eds WB Wood et al, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, USA, pp 415 - 431. http://elegans.swmed.edu/parts/parts.html)
There is not C and a delta type nerve fibers in C. elegans. - We can add to Claim 14 – "the process for stimulating of human and rodent nerve for..."
The efficiency of laser heating by 685 nm is essentially less compared to 980 nm (absorption ~0.04 compared to 0.4-0.43 cm-1).

Nothing in this paper suggest a system or process for used to stimulate a **"single nerve or a portion of a single nerve"** as claimed in the only outstanding independent claim.

Very respectfully,

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